November 14, 2005

0017 '05 NOV 15 A10:32

Division of Docket's Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Madam/Sir,

I submit four copies of this petition as a Citizen under 21 CFR 10.30 or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs, requesting that the Commissioner of Food and Drugs recommend scheduling of tramadol under the Controlled Substances Act.

Action Requested

I request that in view of patient safety and public health considerations noted below, the Commissioner of Food and Drugs recommend scheduling of tramadol under the Controlled Substances Act.

Statement of grounds

I submit the following information as the basis of my request:

1. The attached paper by Dr. Zacny in the November 2005 issue of Drug and Alcohol Dependence [Zacny JP. Drug Alcohol Depend. 2005 Nov 1;80(2):273-8] which provides compelling evidence of the abuse liability of tramadol and recommends that "it would be worthwhile to revisit the issue of abuse liability of tramadol in opiate abusers". The author also concludes that "the present results indicating a clinically prescribed dose of oral tramadol has abuse liability-related effects in recreational drug users suggests the need for further abuse liability testing of the oral formulation in opioid abusers."
2. Single dose studies of tramadol significantly underestimate the abuse liability of the drug, since tramadol's principal active (M1) metabolite is approximately 100 times more potent than the parent drug in producing opioid analgesia (Ultram Package Insert) and this effect is route specific. This means that accurate studies of tramadol's abuse liability must involve repeated dosing with oral tramadol.
3. The single dose studies conducted two decades ago are not representative of repeated administration with long-acting or sustained release formulations for the treatment of chronic pain, where there is frequently co-morbid psychopathology.

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4. Extensive data from animal "abuse liability" studies that clearly indicate that tramadol produces both physical and psychological dependence.
5. Epidemiologic data collected by the National Survey on Drug Use and Health, the American Association of Poison Control Centers Toxic Exposure Surveillance System and the Drug Abuse Warning Network all support the propensity of this drug to be abused and misused.
6. Spontaneous reports to FDA's MEDWATCH program and in the literature provide further evidence of abuse.

Environmental Impact

According to 21 C.F.R. § 25.31(a), this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

Economic Impact Statement

According to 21 C.F.R. § 10.30(b), petitioner will, upon request by the Commissioner, submit economic impact information.

Certification

I certify to my best knowledge and belief that this petition includes all information and views on which the petition relies, and that it includes representative data and information unfavorable to the petition.

Notices regarding this petition should be addressed to:
Rosei Rocha-Judd
2217 2ND Ave N
#304
Birmingham, AL 35203
(404) 409-3794

Respectfully,

Rosei Rocha-Judd

Attachment:

Zacny JP. Profiling the subjective, psychomotor, and physiological effects of tramadol in recreational drug users. Drug Alcohol Depend. 2005;80:273-8